DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 742 and 774

[Docket No. 220516-0114]

RIN 0694-AI21

Commerce Control List: Controls on Certain Marine Toxins

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: The Bureau of Industry and Security (BIS), Department of Commerce, maintains controls on the export, reexport and transfer (in-country) of dual-use items and less sensitive military items through the Export Administration Regulations (EAR), including the Commerce Control List (CCL). This rule proposes new unilateral export controls on four naturally occurring, dual-use biological toxins (specifically, the marine toxins brevetoxin, gonyautoxin, nodularin and palytoxin), the synthesis and collection of which BIS has identified for evaluation according to the criteria in Section 1758 of the Export Control Reform Act of 2018 (ECRA) pertaining to emerging and foundational technologies. These toxins have the potential (through either accidental or deliberate release) to cause casualties in humans or animals, degrade equipment, or damage crops or the environment. As these toxins are now capable of being more easily isolated and purified due to novel synthesis methods and equipment, the absence of export controls on such toxins could be exploited for biological weapons purposes. To address this concern, BIS proposes to amend the CCL by adding these toxins to Export Control Classification Number (ECCN) 1C351. This rule also proposes several conforming changes to the EAR to reflect the proposed addition of these marine toxins to ECCN 1C351. In addition, this document requests public comments to ensure that the scope of these proposed controls will be effective and appropriate (with respect to their potential impact on legitimate commercial or scientific

applications).

DATES: Comments must be received by BIS no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by docket number BIS-2022-0013 or RIN 0694-AI21, through any of the following:

- *Federal eRulemaking Portal:* http://www.regulations.gov. Follow the instructions for submitting comments. You can find this proposed rule by searching for its regulations.gov docket number, which is BIS-2022-0013.
- *E-mail*: PublicComments@bis.doc.gov. Include RIN 0694-AI21 in the subject line of the message.

All filers using the portal or e-mail should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. The corresponding non-confidential version of those comments must be clearly marked "PUBLIC." The file name of the non-confidential version should begin with the character ''P." The "BC" and "P" should be followed by the name of the person or entity submitting the comments. Any submissions with file names that do not begin with a "P" or "BC" will be assumed to be public and will be made publicly available through http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: For questions on the chemical and biological (CB) controls that would apply to the marine toxins proposed for control under ECCN 1C351, contact Dr. Tara Gonzalez, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-3343, E-mail: Tara.Gonzalez@bis.doc.gov. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-6057, E-mail: RPD2@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

Identification of Section 1758 Technologies

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law No. 115-232, Congress enacted the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801-4852. Section 1758 of ECRA (as codified under 50 U.S.C. 4817) authorizes the Bureau of Industry and Security (BIS) to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies that are essential to the national security of the United States.

Neither Section 1758 nor any other section of ECRA defines the terms "emerging technology" or "foundational technology." Further, ECRA does not provide guidance on how to differentiate between "emerging technology" and "foundational technology." Since ECRA's enactment, BIS has solicited public comment on these two terms with the idea that defining the terms would assist in the identification of the technologies. To that end, BIS published numerous rules adding technologies to the CCL pursuant to Section 1758 without defining either term. Notably, pursuant to Section 1758, on November 19, 2018, BIS published an advance notice of proposed rulemaking, "Review of Controls for Certain Emerging Technologies" (83 FR 58201) (November 19 ANPRM). The November 19 ANPRM identified biotechnology in a

representative list of fourteen technology categories concerning which BIS sought public comment to determine whether there are specific emerging technologies that are essential to U.S. national security and for which effective controls can be implemented. The biotechnology-related comments submitted to BIS in response to its November 19 ANPRM did not specifically address the question of export controls on marine toxins and, consequently, this proposed rule does not address those comments. Since the publication of the November 19 ANPRM, BIS has published several rules imposing controls on emerging technologies and advance notices of proposed rulemaking that requested the public to comment on potential emerging technologies. Additionally, on August 27, 2020, BIS published an advance notice of proposed rulemaking (85 FR 52934) (August 27 ANPRM) that sought public comment on the definition of, and criteria for, identifying foundational technologies. BIS has found, however, that the categorization of the technologies has sometimes delayed the imposition of controls. Further, ECRA does not mandate that BIS define either term nor does ECRA require that either of the two categories be treated differently from the other.

Distinguishing Between Emerging and Foundational Technologies

Based on its prior experience with implementing the requirements of Section 1758 of ECRA, in making future determinations, BIS will not characterize a specific technology as "emerging" or "foundational" for purposes of Section 1758 of ECRA. Instead, BIS will characterize all technologies identified pursuant to Section 1758 as "Section 1758 technologies" without drawing a distinction between "emerging" or "foundational" technologies. This characterization will not affect the designation of "critical technologies," for purposes of Committee on Foreign Investment in the United States (CFIUS) screenings, because technologies identified pursuant to Section 1758 of ECRA are "critical technologies," pursuant to 50 U.S.C. 4565(a)(6)(A)(vi), regardless of whether such technologies are characterized as "emerging" or "foundational." This characterization will also not affect the scope of controls on any technologies controlled consistent with Section 1758 of ECRA.

BIS is adopting this approach based on, among other sources, consultations with its interagency partners and a review of certain comments submitted in response to the November 19 ANPRM and the August 27 ANPRM, which sought public comment on "emerging" and "foundational" technologies, respectively.

One key consideration drawn from BIS and interagency experience is that technologies cannot always be readily categorized as either "emerging" or "foundational" technologies. A technology may be "foundational" in the sense of constituting an iterative improvement on technology already in production and use by one company, but simultaneously be "emerging" if such technology is only in the "development" stage (hence not in use) by other manufacturers. These challenges apply to the technologies that are the subject of this proposed rule.

Specifically, the four marine toxins (brevetoxin, gonyautoxin, nodularin and palytoxin) addressed in this proposed rule are naturally occurring and are not necessarily considered, by themselves, to be "emerging" technologies. Consequently, they could be evaluated as "foundational," rather than "emerging" technologies. However, the synthesis and collection of these toxins could be evaluated as an "emerging" technology. Specifically, these toxins can now be more easily isolated and purified due to novel synthesis methods and equipment and, therefore, are capable of being more easily exploited for biological weapons purposes than in the past.

This proposed rule demonstrates some of the difficulties in attempting to draw meaningful and functional distinctions between "emerging" and "foundational" technologies, for the purpose of applying the criteria in "Section 1758" of ECRA to identify technologies essential to the national security of the United States that fall within the scope of this section. Similar challenges have made it difficult to characterize other technologies that have been proposed for addition to the Commerce Control List (CCL), Supp. No. 1 to part 774 of the EAR, pursuant to Section 1758 as "emerging" or "foundational." Rather than attempting to continue to distinguish which new controls implemented pursuant to Section 1758 are "emerging" or "foundational,"

BIS believes the government's resources and the mandate from Congress are better served identifying the technologies essential to U.S. national security under Section 1758.

BIS received several comments in response to the August 27 ANPRM that specifically requested that BIS set specific parameters by which foundational technologies would be defined. However, BIS does not believe the proposed parameters provided a meaningful distinction from "emerging" technologies. While BIS will not specify that a particular item is either "foundational" or "emerging" technology, it will continue to be informed by, among other things, the Statement of Policy in Section 1752 of ECRA (50 U.S.C. 4811), the reasons for control described in part 742 of the EAR, and relevant factors described in the November 19 and August 27 ANPRMs. Additionally, the identification of such technologies will take into account the statutory criteria in Section 1758(a)(2)(B) of ECRA: (i) the development of the emerging and foundational technologies in foreign countries; (ii) the effect export controls imposed pursuant to this section may have on the development of such technologies in the United States; and (iii) the effectiveness of export controls imposed pursuant to this section on limiting the proliferation of the emerging and foundational technologies in foreign countries.

Referring to these items as "Section 1758 technologies" without attempting to categorize individual technologies as "emerging" or "foundational" technology is consistent with the requirements of Section 1758, will facilitate more efficient interagency review of implementing regulations, and result in more timely implementation of such controls. As noted above, ECRA neither defines nor requires distinguishing between emerging and foundational technologies and there is no impact on the scope of controls on technologies whether they are described as emerging or foundational.

The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process, and in doing so, must consider the potential end-uses and end-users of emerging and foundational technologies, and the countries to which exports from the United States are restricted (e.g.,

embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum a license must be required for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

In addition, Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)) requires that the interagency process for identifying Section 1758 technologies include a notice and comment period. Consequently, this proposed rule seeks public comments concerning the application of the criteria set forth in ECRA Section 1758(a)(2), as well as the factors described above, to the proposed controls on four marine toxins as described below.

Proposed Section 1758 Controls on Four Marine Toxins

The synthesis and collection of four marine toxins (brevetoxin, gonyautoxin, nodularin and palytoxin) has been identified for evaluation, consistent with the interagency process described in Section 1758 of ECRA. This identification is based on a finding that, although these toxins are naturally occurring, dual-use biological toxins, they have the potential (through either accidental or deliberate release) to cause casualties in humans or animals, degrade equipment, or damage crops or the environment. As these toxins can now be more easily isolated and purified due to novel synthesis methods and equipment, the absence of export controls on such toxins could be exploited for biological weapons purposes.

Proposed amendments to ECCN 1C351.

Consistent with BIS's authority to evaluate the level of controls that would be appropriate for the export, reexport or transfer (in-country) of emerging technologies, this rule proposes to amend the CCL by adding the aforementioned marine toxins to ECCN 1C351.d. These toxins are not currently included on any of the Australia Group (AG) Common Control Lists – consequently, the Chemical/Biological (CB) controls that would apply to these toxins, as proposed by this rule, would be unilateral, absent the adoption of comparable controls by the AG. The toxins also would be controlled by ECCN 1C351.d for anti-terrorism (AT) reasons. The four marine toxins proposed for control by this proposed rule are described below.

Brevetoxins are neurotoxins produced by the marine dinoflagellate Karenia brevis[1] that bind to the voltage-gated sodium channels in nerve cells, leading to a disruption of normal neurological processes and causing neurotoxic shellfish poisoning. The potent neurotoxic and hemolytic properties of these neurotoxins can be fatal to fish, aquatic mammals, birds, and humans (although no fatalities have yet to be reported for humans[2]).

Gonyautoxins are part of the group of saxitoxins (currently controlled under ECCN 1C351.d.12) that are naturally produced in several marine dinoflagellates species.[3] Certain forms are included under Schedule 1 of the Chemical Weapons Convention (CWC) Annex on Chemicals. Gonyautoxins can bind to the α-subunit of the voltage dependent sodium channels in the postsynaptic membrane, blocking synaptic function (the transmission of nerve impulses between neurons or between neurons and muscle cells) and causing paralytic shellfish poisoning. Paralytic shellfish poisoning includes symptoms such as nausea, vomiting, dizziness, limb weakness, paralysis, or respiratory failure and can result in death.[4]

Nodularins are potent toxins that may cause irreversible liver damage.[5] Naturally produced in cyanobacteria, nodularin shares significant structural homology and, presumably, function with microcystins[6] (currently controlled under ECCN 1C351.d.9). Microcystins have been studied extensively, and due to the homology with nodularin, these data are often extended to nodularins.

Palytoxins are naturally produced in certain corals and dinoflagellates. These toxins are among the most toxic non-protein compounds and are of particular concern due to their

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[1] Shen, H. H., et al. "Profiling of Brevetoxin Metabolites Produced by Karenia Brevis 165 Based on Liquid Chromatography-Mass Spectrometry." *Toxins* 13.5 (2021).

[2] Per the NIH National Library of Medicine, National Center for Biotechnology Information.

[3] Visciano, P., et al. "Marine Biotoxins: Occurrence, Toxicity, Regulatory Limits and Reference Methods." *Frontiers in Microbiology* 7 (2016).

[4] Clark, RF; Williams, SR; Nordt, SP; Manoguerra, AS (1999). "A review of selected seafood poisonings." Undersea & Hyperbaric Medicine. 26 (3): 175–84.

[5] Dawson, R. M. "The Toxicology of Microcystins." Toxicon. 36 (7): 953–962. (1998) doi:10.1016/S0041-0101(97)00102-5.

[6] Gehringer, M., et al. Nodularin, a cyanobacterial toxin, is synthesized in planta by symbiotic *Nostoc* sp.. *ISME* J 6, 1834–1847 (2012). https://doi.org/10.1038/ismej.2012.25.

thermostability and effective inhalation exposure route.[7] Palytoxins target the sodium-potassium pump protein, which may lead to vasoconstriction (the constriction of blood vessels through tightening of the small muscles in their walls). The most frequently reported routes of exposure/entry are through inhalation, ingestion, or via the cutaneous route (i.e., direct contact with the skin or eyes). The symptoms of palytoxin poisoning, which may vary according to the route of exposure, include nausea, vomiting, diarrhea, lethargy, numbness, muscle spasms, slow heart rate, respiratory distress or kidney failure and can result in death. In lethal cases, death is generally caused by cardiac arrest.

This rule proposes to add these marine toxins, in alphabetical order, to ECCN 1C351.d and to amend the introductory text of 1C351.d by removing the reference to the AG control list (thereby reflecting the fact that these marine toxins would be subject to unilateral controls, absent the adoption of comparable controls by the AG). This rule also proposes to make conforming changes elsewhere in ECCN 1C351 to update references to certain toxins (i.e., in the CW Reason for Control paragraph, License Requirements Notes 1 and 2, the License Exception STA eligibility paragraph and the Related Controls paragraph). The proposed conforming amendments to the Chemical Weapons Convention (CWC) and License Exception Strategic Trade Authorization (STA) provisions in the EAR are described below.

Proposed expansion of ECCN 1E001 controls.

Although this rule does not propose to amend ECCN 1E001 (which controls, *inter alia*, "technology" for the "development" or "production" of the human and animal pathogens and "toxins" described in ECCN 1C351), the heading of ECCN 1E001 indicates that, with limited exceptions, ECCN 1E001 controls "technology for the "development" or "production" of items listed under Category 1C of the CCL. Consequently, if the changes proposed in this rule were to go into effect, ECCN 1E001 would control "technology" for the "development" or "production"

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[7] Ramos V, et al. "Palytoxin and analogs: biological and ecological effects." *Marine Drugs*. 8 (7): 2021–37. (2010) doi:10.3390/md8072021.

of the four marine toxins that would be added to ECCN 1C351. This expansion in the scope of ECCN 1E001 would be unilateral in nature, absent the adoption of comparable controls by the AG.

Other conforming amendments to reflect the proposed reordering of toxins in ECCN 1C351.d.

This rule proposes to amend § 740.20—License Exception Strategic Trade Authorization (STA) to make conforming changes to the ECCN 1C351.d references in paragraph (b)(2)(v) and paragraph (b)(2)(vi). Specifically, § 740.20(b)(2)(v) would be amended to reference the exclusion of ECCN 1C351.d.15 and d.16 items from License Exception STA eligibility, consistent with the proposed renumbering of ricin and saxitoxin (which are currently controlled under ECCN 1C351.d.11 and d.12, respectively). Similarly, § 740.20(b)(2)(vi) would be amended, consistent with the proposed renumbering of the toxins in ECCN 1C351.d, by revising the references to the ECCN 1C351.d toxins that are authorized (with certain limitations) under License Exception STA to destinations indicated in Country Group A:5 (see Supplement No. 1 to part 740 of the EAR).

This rule also proposes to make conforming changes to § 742.18—Chemical Weapons Convention (CWC) and ECCN 1C991 (Vaccines, immunotoxins, medical products, diagnostic and food testing kits) to reflect the proposed renumbering of the toxins in ECCN 1C351.d. Specifically, § 742.18(a)(1), (b)(1)(i), and (b)(1)(ii) and (iii) would be amended to reference ECCN 1C351.d.15 and d.16, consistent with the proposed renumbering of ricin and saxitoxin described above. ECCN 1C991.c through 1C991.e would be amended to make conforming changes to the references therein to ECCN 1C351 that would be affected by the proposed renumbering of the toxins in ECCN 1C351.d.

None of the proposed conforming amendments described above would change the scope of the controls in the affected EAR provisions.

Request for Comments

BIS is publishing this proposed rule to obtain public comments on the proposed

application of CB controls to the four marine toxins that are proposed for addition to ECCN 1C351 and to "technology" for the "development" or "production" of such toxins that would satisfy the control parameters described in ECCN 1E001. Consistent with Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), this proposed rule provides the public with notice and the opportunity to comment on controlling this technology as described herein. Specifically, BIS welcomes any comments on this proposed rule relevant to the following:

(1) Whether the proposed controls are clear and adequately identify "emerging and foundational technologies" within the context of biological weapons-related capabilities and developments (to the extent that this is not the case, comments should include specific control text that would be more appropriate to these ends);

(2) The current capability for the "development" or "production" of such toxins in the United States and other countries, including the extent to which the proposed controls would affect current production or sales of such toxins, either within or outside the United States (e.g., whether the proposed controls would inadvertently control any toxins that are suitable almost exclusively for legitimate commercial or scientific applications);

(3) The effect that implementation of the proposed controls would have on the future "development" or "production" of such toxins and related "technology" in the United States; and

(4) The effectiveness of the proposed controls in terms of limiting the proliferation of such toxins and related "technology" abroad.

BIS also welcomes comments concerning whether these controls should be implemented multilaterally (rather than unilaterally), in the interest of increasing their effectiveness and minimizing their impact on U.S. industry. Several respondents who commented on BIS's November 19 ANPRM indicated their preference for multilateral export controls over unilateral export controls, because the former typically place U.S. industry on a more level playing field versus producers/suppliers in other countries. In this regard, note that Section 1758(c) of ECRA (50 U.S.C. 4817(c)) provides that "the Secretary of State, in consultation with the Secretary [of

Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to subsection (a) [of ECRA] [which addresses the interagency process for identifying emerging technologies] be added to the list of technologies controlled by the relevant multilateral export control regimes."

Public comments submitted to BIS in response to this proposed rule will help BIS and other U.S. Government agencies to apply the criteria set forth in Section 1758 of ECRA and identify and assess the appropriate level of controls that should apply to the four marine toxins proposed for control under ECCN 1C351 and "technology" for the "development" or "production" of such toxins, as proposed for control under ECCN 1E001.

Comments should address specific aspects of the proposed addition of these toxins to ECCN 1C351 on the CCL in relation to the criteria described above (e.g., identify the specific aspects in which the proposed controls would satisfy these criteria or fail to do so). Comments should be submitted to BIS as described in the ADDRESSES section of this proposed rule and must be received by BIS no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Export Control Reform Act of 2018

The Export Control Reform Act of 2018 (ECRA), as amended, codified at 50 U.S.C. 4801–4852, serves as the authority under which BIS issues this proposed rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This proposed rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866.

Accordingly, this proposed rule has been reviewed by the Office of Management and Budget (OMB).

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This proposed rule contains the following collections of information subject to the requirements of the PRA:

- OMB control number 0694–0088 (Simplified Network Application Processing System) – this collection includes license applications and carries a burden estimate of 29.6 minutes per manual or electronic submission;
- OMB Control Number 0694-0096 (Five Year Records Retention Period) – this collection includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response;
- OMB Control Number 0607-0152 (Automated Export System (AES) Program) – this collection carries a burden hour estimate of 3 minutes per electronic submission and contains the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES).

Although this proposed rule would make important changes to the EAR for items controlled for CB reasons, BIS believes that these increases would not greatly exceed existing estimates. BIS does believe the number of applications will increase by 15 because, although there are few (if any) commercial applications for these marine toxins, a small number of these toxins may be exported for use in research and development activities. BIS requests comments concerning the anticipated increase in burden hours and costs as a result of the changes proposed by this rule. Comments on the methodology associated with calculating the cost or burden increases, or any other aspect of this collection, may be submitted via www.regulations.gov by

searching for OMB Control Number 0694-0088.

BIS expects the burden hours associated with OMB control numbers 0694-0088 and 0694-0096 to increase by 7 hours and 39 minutes (i.e., 15 applications × 30.6 minutes per response) for a total estimated cost increase of $230 (i.e., 7 hours and 39 minutes × $30 per hour). The $30 per hour cost estimate for OMB control number 0694-0088 is consistent with the salary data for export compliance specialists currently available through glassdoor.com (glassdoor.com estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). Note that any increase in the burden hours associated with OMB control number 0607-0152 would not necessarily be in direct correlation with any increase in the aforementioned OMB information collections, because there could be multiple shipments (and, hence, multiple EEI filings) associated with an individual export license.

3. This proposed rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date. Notwithstanding, BIS believes this proposed rule would benefit from public comment prior to issuance. Consistent with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq*.), BIS has prepared the following initial regulatory flexibility analysis (IRFA) of the impact that this proposed rule, if adopted, would have on small businesses.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this proposed rule are discussed in the background section of the preamble of this document and, consequently, are not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of All

Relevant Federal Rules Which May Duplicate, Overlap or Conflict with the Proposed Rule

The objective of this proposed rule, and all other Section 1758 technology proposed rules published by BIS, is to control emerging and foundational technologies identified by BIS and its interagency partners as being essential to U.S. national security. The legal basis for this proposed rule is as follows: 50 U.S.C. 4801-4852.

No other Federal rules duplicate, overlap, or conflict with this proposed rule.

Number and Description of Small Entities Regulated by the Proposed Action

This proposed rule would apply to all persons engaged in the export, reexport or transfer (in-country) of the marine toxins proposed for control under ECCN 1C351 and the related "technology" subject to the EAR. Presently, these toxins and related "technology" are used in research and development activities in the biotechnology field (e.g., U.S. university and military laboratories). Therefore, BIS anticipates that the proposed controls would result in 'deemed' export license applications (for the release of "technology" to foreign nationals located within the United States) to allow access to this "technology" by foreign students and faculty at U.S. universities, as well as by non-U.S. employees of U.S. biochemical firms. There would most likely also be 'deemed' reexport license applications for the release of this "technology" to third-country foreign nationals located in foreign countries who are engaged in research and development activities involving this "technology."

BIS does not collect or maintain the data necessary to determine how many of the affected persons are small entities as that term is used by the Small Business Administration. Prior to issuing this proposed rule, BIS received 36 comments on biotechnology in response to its November 19 ANPRM. None of these commenters specifically identified themselves as small businesses, although small businesses may have chosen to provide input through larger entities, such as trade associations.

However, BIS was able to estimate the number of license applications that the agency

anticipates receiving as a result of this proposed rule and is using that estimate as a means of assessing the impact on small businesses. Using the North American Industry Classification System Codes (NAICS) 541714 (Research and Technology in Biotechnology (except Nanobiotechnology)), BIS determined that the standard small business size in this industry is 1,000 employees. Using Table 1a of the Census Bureau's 2019 Exports by Company Type and Employment Size and extrapolating to 1,000 employees, BIS then estimated that approximately 40% of all identified companies that export in this industry are small businesses. BIS also estimates that it will receive 15 license applications per year for the items described in this proposed rule (see the PRA estimates described in Rulemaking Requirements #2, above). Based on that information, BIS estimates that the agency will receive approximately 6 license applications per year from small businesses, or roughly 40% of the 15 estimated license applications.

In addition, based on the burden estimate for OMB under control numbers 0694–0088 (Simplified Network Application Processing System) and 0694-0096 (Five Year Records Retention Period), BIS expects that the total burden hours for small businesses associated with these EAR-related collections would increase only slightly, by just under 3 hours and 4 minutes (i.e., 6 applications × 30.6 minutes per response), for a total estimated cost increase of just under $92 (i.e., 3 hours and 4 minutes × $30 per hour).

The amendments proposed in this rule, if implemented, also would trigger a small information collection burden under the U.S. Census Bureau's Foreign Trade Regulations (FTR) (15 CFR part 30), which contain the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES). This FTR-related information collection has been approved by OMB under control number 0607-0152 (Automated Export System (AES) Program) and carries a burden hour estimate of 3 minutes per electronic submission. This collection, together with the aforementioned EAR-related information collections, would result in a total estimated cost increase to small businesses of just under $94 (i.e., 3 hours and 7

minutes × $30 per hour). Note that, for purposes of consistency, the $30 per hour cost estimate used for the EAR-related information collections described above is also applied to this FTR-related information collection (which also would involve work performed by export compliance specialists).

Based on the analysis provided above, the amendments proposed in this rule would not impose a significant economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes proposed in this rule, if adopted, would mean that certain items currently eligible for export, reexport or transfer (in-country) to most destinations under the No License Required (NLR) designation would require an EAR authorization (i.e., in accordance with the terms and conditions of an EAR license exception or a license issued by BIS). Adding these items to the CCL, to be controlled under ECCN 1C351, may also change the export clearance requirements under the FTR for certain exports of these items by triggering an EEI filing requirement in AES (note that the requirement generally does not apply to items below a certain value that are classified as EAR99, i.e., subject to the EAR, but not listed under an ECCN on the CCL).

To the extent that compliance with the changes proposed in this rule would impose a burden on persons, including small businesses, BIS believes the burden would be minimal. The reclassification process would need to be done only once per license applicant for exports, reexports or transfers (in-country) of these emerging technology items and, consequently, would constitute a one-time burden for each applicant. Similarly, assessing the availability of license exceptions and/or applying for and using BIS licenses would impose some minimal burden on persons, including small businesses.

However, it should be noted that these EAR requirements would likely have less impact

than might otherwise be the case, because of the resources that BIS makes available to all exporters, including small businesses. Specifically, BIS's website has free on-line training explaining export basics, including instructions on how to register for and use BIS's online license application tool, and tips on how to complete a license application for chemical and biological items. BIS also provides free export counseling by telephone and e-mail via both its Washington, DC and Western Regional offices. In addition, BIS accepts requests for commodity classifications and processes them without charge to assist those exporters who need assistance in classifying their items for the purpose of determining whether any CCL-based license requirements would apply.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the amendments proposed in this rule, if published in a final rule, would have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these proposed amendments to assess whether the alternatives would: (1) accomplish the stated objectives of this proposed rule (consistent with the emerging technology requirements in ECRA); and (2) minimize any significant economic impact of this proposed rule on small entities. BIS could have proposed a much broader control on marine toxins controlled under ECCN 1C351 that would have captured a greater number of such toxins. However, that option would have had a greater impact not only on small businesses, but also on research and development laboratories (both academic and corporate), which are involved in advancing biological technology. BIS has determined that proposing focused controls on those marine toxins capable of posing a greater risk to human/animal health and the environment (i.e., the four toxins proposed for control under ECCN 1C351 and corresponding "development" and production "technology" in ECCN 1E001) is the least disruptive alternative for implementing export controls in a manner consistent with controlling technology that has been determined, through the Section 1758 technology interagency process authorized under ECRA, to be

essential to U.S. national security.

BIS is not proposing different compliance or reporting requirements for small businesses. If a small business is subject to a compliance requirement for the export, reexport or transfer (in-country) of this "software" and related "technology," then it would submit a license application using the same process as any other company (i.e., electronically via SNAP-R). The license application process is free of charge to all entities, including small businesses. In addition, as noted above, the resources and other compliance tools made available by BIS typically serve to lessen the impact of any EAR license requirements on small businesses.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and also considered whether an exemption for small businesses was practical under the circumstances (i.e., within the context of the changes proposed in this rule).

BIS determined that the use of design standards was the most appropriate approach for regulating exports/reexports of these toxins. Although the marine toxins that warrant control under this proposed rule are naturally occurring, dual-use biological toxins, they can now be more easily isolated and purified due to novel synthesis methods and equipment. For this reason, the absence of export controls on such toxins could be exploited for biological weapons purposes. However, because these toxins and related "technology" are dual-use items, they also have legitimate commercial and scientific applications. Consequently, controlling these toxins and the related "technology" based on design standards is the most appropriate way to impose export controls in a manner that would enhance U.S. national security, but also consider the legitimate commercial and scientific applications for these toxins.

This proposed rule does not contain an exemption for small businesses from this license requirement because BIS and its interagency partners are assessing whether these controls are essential to U.S. national security. Specifically, these toxins and related "technology" could be used for biological weapons purposes and, as such, controlling these items on the CCL may be determined to be essential to U.S. national security pursuant to the interagency process for

identifying emerging and foundational technologies that is described in Section 1758(a) of ECRA (50 U.S.C. 4817(a)). An exemption for small businesses would undermine the effectiveness of these proposed controls.

Conclusion

BIS has identified the synthesis and collection of the marine toxins and the related "technology" addressed in this proposed rule as a technology suitable for evaluation under Section 1758 of ECRA that warrants public notice and comment. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this IRFA addressing the impact that this proposed rule, if adopted, would have on small entities. BIS's assessment indicates that the amendments proposed in this rule would not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this IRFA in accordance with the instructions provided in the "ADDRESSES" section of this proposed rule.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, parts 740, 742 and 774 of the Export Administration Regulations (15 CFR parts 730-774) are proposed to be amended as follows:

PART 740—LICENSE EXCEPTIONS

1. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 22 U.S.C. 7201 *et seq*.; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

2. Section 740.20 is amended by revising paragraph (b)(2)(v) and paragraph (b)(2)(vi) introductory text to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *

(b) * * *

(2) * * *

(v) License Exception STA may not be used for any item controlled by ECCN 1C351.a, .b, .c, .d.15, .d.16 or .e, ECCNs 1C353, 1C354, 1E001 (i.e., for technology, as specified in ECCN 1E001, for items controlled by ECCN 1C351.a, .b, .c, .d.15, .d.16 or .e or ECCNs 1C353 or 1C354) or ECCN 1E351.

(vi) Toxins controlled by ECCN 1C351.d.1 through 1C351.d.14 and 1C351.d.17 through 1C351.d.22 are authorized under License Exception STA to destinations indicated in Country Group A:5 (See supplement no. 1 to part 740), subject to the following limits. For purposes of this paragraph (b)(2)(vi), all such toxins that are sent from one exporter, reexporter or transferor to a single end-user, on the same day, constitute one shipment.

* * * * *

PART 742—CONTROL POLICY—CCL BASED CONTROLS

3. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 22 U.S.C. 3201 *et seq*.; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq*.; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950;

E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

4. Section 742.18 is amended by revising paragraph (a)(1), paragraph (b)(1)(i) introductory text, and paragraphs (b)(1)(ii) and (iii) to read as follows:

§ 742.18 Chemical Weapons Convention (CWC or Convention).

* * * * *

(a) * * *

(1) Schedule 1 chemicals and mixtures controlled under ECCN 1C351. A license is required for CW reasons to export or reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to all destinations including Canada. CW applies to 1C351.d.15 for ricin in the form of Ricinus Communis AgglutininII (RCA_{II}), which is also known as ricin D or Ricinus Communis LectinIII (RCL_{III}), and Ricinus Communis LectinIV (RCL_{IV}), which is also known as ricin E. CW applies to 1C351.d.16 for saxitoxin identified by C.A.S. #35523-89-8. (Note that the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR also apply to exports of Schedule 1 chemicals.)

* * * * *

(b) * * *

(1) * * *

(i) *Exports to States Parties to the CWC*. Applications to export Schedule 1 Chemicals controlled under ECCN 1C351.d.15 or .d.16 to States Parties to the CWC (destinations listed in supplement no. 2 to part 745 of the EAR) generally will be denied, unless all of the following conditions are met:

* * * * *

(ii) *Exports to States not party to the CWC*. Applications to export Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to States not Party to the CWC

(destinations not listed in supplement no. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the CWC.

(iii) *Reexports*. Applications to reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 generally will be denied to all destinations (including both States Parties to the CWC and States not Party to the CWC).

* * * * *

PART 774—THE COMMERCE CONTROL LIST

5. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 *et seq*.; 50 U.S.C. 1701 *et seq*.; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq*.; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq*.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

6. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, revise ECCNs 1C351 and 1C991 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

1C351 Human and animal pathogens and "toxins," as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	Country chart (See Supp. No. 1 to part 738)
CB applies to entire entry	CB Column 1

CW applies to 1C351.d.15 and .d.16 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.15 for ricin in the form of (1) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D or Ricinus Communis LectinIII

(RCL_{III}) and (2) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E. CW applies to 1C351.d.16 for saxitoxin identified by C.A.S. #35523-89-8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

Control(s)	Country chart (See Supp. No. 1 to part 738)
AT applies to entire entry	AT Column 1

LICENSE REQUIREMENT NOTES: *1. All vaccines and 'immunotoxins' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under 1C351.d, with the exception of toxins controlled for CW reasons under 1C351.d.15 or .d.16, are excluded from the scope of this entry. Vaccines, 'immunotoxins,' certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.*

2. For the purposes of this entry, only saxitoxin is controlled under 1C351.d.16; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in 1C351.c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1-3), this ECCN controls all biological agents and "toxins," regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or "toxins" that are excluded from the lists of select biological agents or "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.14 and 1C351.d.17 through 1C351.d.22. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.15 and .d.16 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are "subject to the ITAR." (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b)

and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are "subject to the ITAR."

Related Definitions: For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.

Items:

a. Viruses identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

a.1. African horse sickness virus;

a.2. African swine fever virus;

a.3. Andes virus;

a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:

a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*

a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or .a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*

a.5. Bluetongue virus;

a.6. Chapare virus;

a.7. Chikungunya virus;

a.8. Choclo virus;

a.9. Classical swine fever virus (Hog cholera virus);

a.10. Crimean-Congo hemorrhagic fever virus;

a.11. Dobrava-Belgrade virus;

a.12. Eastern equine encephalitis virus;

a.13. Ebolavirus (includes all members of the Ebolavirus genus);

a.14. Foot-and-mouth disease virus;

a.15. Goatpox virus;

a.16. Guanarito virus;

a.17. Hantaan virus;

a.18. Hendra virus (Equine morbillivirus);

a.19. Japanese encephalitis virus;

a.20. Junin virus;

a.21. Kyasanur Forest disease virus;

a.22. Laguna Negra virus;

a.23. Lassa virus;

a.24. Louping ill virus;

a.25. Lujo virus;

a.26. Lumpy skin disease virus;

a.27. Lymphocytic choriomeningitis virus;

a.28. Machupo virus;

a.29. Marburgvirus (includes all members of the Marburgvirus genus);

a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);

a.31. Monkeypox virus;

a.32. Murray Valley encephalitis virus;

a.33. Newcastle disease virus;

a.34. Nipah virus;

a.35. Omsk hemorrhagic fever virus;

a.36. Oropouche virus;

a.37. Peste-des-petits ruminants virus;

a.38. Porcine Teschovirus;

a.39. Powassan virus;

a.40. Rabies virus and all other members of the Lyssavirus genus;

a.41. Reconstructed 1918 influenza virus;

Technical Note: *1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments*.

a.42. Rift Valley fever virus;

a.43. Rinderpest virus;

a.44. Rocio virus;

a.45. Sabia virus;

a.46. Seoul virus;

a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

a.48. Sheeppox virus;

a.49. Sin Nombre virus;

a.50. St. Louis encephalitis virus;

a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);

a.52. Swine vesicular disease virus;

a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus - see 1C351.b.3 for Siberian subtype);

a.54. Variola virus;

a.55. Venezuelan equine encephalitis virus;

a.56. Vesicular stomatitis virus;

a.57. Western equine encephalitis virus; *or*

a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC "select agents" lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

b.1. [Reserved];

b.2. [Reserved]; *or*

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus - see 1C351.a.53 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

c.1. Bacillus anthracis;

c.2. Brucella abortus;

c.3. Brucella melitensis;

c.4. Brucella suis;

c.5. Burkholderia mallei (Pseudomonas mallei);

c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);

c.7. Chlamydia psittaci (Chlamydophila psittaci);

c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;

c.9. Clostridium baratii, botulinum neurotoxin producing strains;

c.10. Clostridium botulinum;

c.11. Clostridium butyricum, botulinum neurotoxin producing strains;

c.12. Clostridium perfringens, epsilon toxin producing types;

c.13. Coxiella burnetii;

c.14. Francisella tularensis;

c.15. Mycoplasma capricolum subspecies capripneumoniae ("strain F38");

c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);

c.17. Rickettsia prowazekii;

c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);

c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;

Note: *Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*

c.20. Shigella dysenteriae;

c.21. Vibrio cholerae; *or*

c.22. Yersinia pestis.

d. "Toxins," as follows, or their subunits:

d.1. Abrin;

d.2. Aflatoxins;

d.3. Botulinum toxins;

d.4. Brevetoxin;

d.5. Cholera toxin;

d.6. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;

d.7. Conotoxins;

d.8. Diacetoxyscirpenol;

d.9. Gonyautoxin;

d.10. HT-2 toxin;

d.11. Microcystins (Cyanginosins);

d.12. Modeccin;

d.13. Nodularin;

d.14. Palytoxin;

d.15. Ricin;

d.16. Saxitoxin;

d.17. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);

d.18. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);

d.19. T-2 toxin;

d.20. Tetrodotoxin;

d.21. Viscumin (Viscum album lectin 1); *or*

d.22. Volkensin.

e. "Fungi", as follows:

e.1. Coccidioides immitis; *or*

e.2. Coccidioides posadasii.

* * * * *

1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country Chart (See Supp. No. 1 to part 738)
CB applies to 1C991.c	CB Column 3
AT applies to entire entry	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License

Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

(a) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D, or Ricinus Communis LectinIII (RCL_{III});

(b) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E; *or*

(c) Saxitoxin identified by C.A.S. #35523-89-8.

(2) The export of a "medical product" that is an "Investigational New Drug" (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.

(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

Related Definitions: For the purpose of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, 'medical products' are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions; (2) prepackaged for distribution as clinical or medical products; and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an "Investigational New Drug" (IND) (see 21 CFR part 312). For the purpose of this entry, 'diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including

bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, 'vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

Technical Note: *For purposes of the controls described in this ECCN, 'toxins' refers to those toxins, or their subunits, controlled under ECCN 1C351.d.*

a. Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.

b. Immunotoxins containing toxins controlled by 1C351.d;

c. Medical products that contain any of the following:

c.1. Toxins controlled by ECCN 1C351.d (except for botulinum toxins controlled by ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.7, or items controlled for CW reasons under ECCN 1C351.d.15 or .d.16); *or*

c.2. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 (except for those that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7);

d. Medical products not controlled by 1C991.c that contain any of the following:

d.1. Botulinum toxins controlled by ECCN 1C351.d.3;

d.2. Conotoxins controlled by ECCN 1C351.d.7; *or*

d.3. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.7;

e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (except for items controlled for CW reasons under ECCN 1C351.d.15 or .d.16).

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary

for Export Administration.

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